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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,920	07/24/2001	Cho-Chou Kuo	41548	2753

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EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/910,920	KUO ET AL.	
	Examin r	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication app ars on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 8-19* is/are pending in the application.

4a) Of the above claim(s) *9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4,6 and 8-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. The amendment filed on 12/10/02 has been entered into the record. Claims 5 and 7 have been canceled. Claim 1 has been amended. New claims 17 and 18 have been added. Claims 9-16 have been withdrawn from consideration. New claims have been added to the elected invention, said election being made in paper# 8. Claims 1-4, 6, 8 and 17-18 are under examination with respect to mannose-6-phosphate, a mannose-6-phosphate receptor, or an insulin-like- growth factor.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

3. The rejection of claims 1 and 8 under 35 U.S.C. 102 (b) as being anticipated by Kuo et al 1996 is maintained as set forth in the previous office action (paper # 9).

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with mannose-6-phosphate or mannose –6-phosphate receptor and a pharmaceutical carrier, diluent or excipient, said molecule comprises mannose-6-phosphate.

Kuo et al. (J.Clin.Invest, Vol. 98(12) pp. 2813-2818) disclose a composition comprising a high mannose type oligosaccharide from Chlamydia MOMP and hen ovalbumin. Pretreatment of Hela cells with high mannose type oligosaccharide inhibited infectivity effectively (see abstract, Table III, figure 2 and 3, page 2816, right column through 2817). The limitation pharmaceutical carrier or a diluent read on water or buffer A (see page 2814, right column under preparation of glycolipids). The disclosed pretreated Hela cells with oligosaccharides interact with mannose-6-phosphate. Thus the prior art anticipated the claimed invention.

Applicants' arguments filed on 12/10/02, have been fully considered but they are not deemed to be persuasive.

Applicant states that Kuo et al does not teach mannose-6-phosphate and teach multiple mannose residues.

It is the position of the Office that the claims are not rejected because Kuo et al disclose mannose –6-phosphate. The claims are rejected because the prior art discloses a composition comprising a high mannose type oligosaccharide associated with MOMP and this composition inhibited infectivity of Chlamydia in Hela cells (see Figures 2 and 3). Therefore, this rejection is maintained.

4. The rejection of claims 1-4, 6 and 8 under 35 U.S.C. 102 (b) as being anticipated by Ooij et al 1997 is maintained as set forth in the previous office action (paper # 9).

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with mannose-6-phosphate, a mannose-6-phosphate receptor, said molecule is an antibody that specifically binds to mannose-6-phosphate, a mannose-6-phosphate receptor in a pharmaceutical composition.

Ooij et al (Infect. Immun. 1997 Vol. 65(2) pp. 758-766) disclose a composition comprising a monoclonal antibody to mannose-6-phosphate receptor (see page 759, left column, second paragraph) in a pharmaceutical composition i.e., PBS (see page 759, left column last three lines of last paragraph). In infected cells, Chlamydial vacuole was shown to bind to antibodies to mannose-6-phosphate receptor (CI-M6PR) and has been shown to be involved in replication (Discussion, last paragraph). CI-M6PR binds to mannose-6-phosphate residues on proteins in the TGN (see page 760, left column 3rd paragraph). The prior art anticipated the claimed invention.

Applicants' arguments filed on 12/10/02, have been fully considered but they are not deemed to be persuasive.

Applicant states that Ooij et al et al used antibodies in vitro as markers of endosomes and thus antibodies are not specific for Chlamydia-infected cells. The examiner disagrees with the applicant because Ooji et al disclosed Hela cells infected with L2 serovars stained with an

antibody to CI-M6PR (please note page 760, left column, third paragraph). Therefore, antibodies are specific for Chlamydia-infected cells. Hence, this rejection is maintained.

5. The rejection of claims 1-8 under 35 U.S.C. 102 (a) as being anticipated by Lin et al 2001 in the previous office action is applied to the newly amended claims 17-18. The rejection is applied because the Declaration is defective. The Declaration is not submitted under 37C.F.R 1.131. Therefore, appropriate declaration (37C.F.R 1.131 or 37C.F.R 1.132 see MPEP 715.01) is required to remove the publication as a reference under 102 (a).

New Rejections Based on the Amendment

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected as being vague for the recitation of " molecule comprises mannose-6-phosphate". It is not clear how Chlamydia infection inhibiting molecule comprising mannose-6-phosphate interacts with mannose-6-phosphate?

8. Claims 17-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Ooij et al 1997.

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with insulin-like- growth-factor-2 (IGF-2) in a pharmaceutical composition, said molecule an antibody.

Ooij et al. (Infect. Immun. 1997 Vol. 65(2) pp. 758-766) disclose a composition comprising monoclonal antibody to mannose-6-phosphate receptor (see page 759, left column, second paragraph) in a pharmaceutical composition i.e., PBS (see page 759, left column last three lines of last paragraph). This antibody binds to infected C.trachomatis cells that contain mannose-6-phosphate receptors. It is known that IGF-2 binds to mannose-6-phosphate receptor (IGF-2/Man6-p receptor, see Specification pages 4-5). Therefore, antibodies to mannose-6-phosphate receptor would interact with IGF-2 in infected Hela cells. Hence, this composition (antibody treated infected Hela cells) read on the claimed Chlamydia infection inhibiting amount of molecule. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 17-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peterson et al 1998 (Infect. Immun. Vol. 66(8) pp3848-3855).

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with insulin-like- growth-factor-2 (IGF-2) in a pharmaceutical composition, said molecule an antibody.

Peterson et al (Infect. Immun. 1998) disclose a composition comprising a monoclonal antibody Mab CP-33. This antibody neutralized the infectivity of Chlamydia pneumoniae (see abstract and figure 4). Therefore, the disclosed antibody meets the limitation "a composition comprising Chlamydia inhibiting amount of a molecule". Pharmaceutical carrier or diluent read on medium or water or PBS (see page 3849 right column, under in vitro neutralization assay). Mab CP-33 specifically binds to Chlamydia (see discussion, page 3852, right column, second paragraph, Table 1 and 2) and neutralizes the infection. Therefore, it is inherent that this

antibody interacts with insulin-like- growth-factor-2 present in Chlamydia and thereby neutralizes the infectivity because Hep-2 or Hela cells that contain mannose-6-phosphate receptor inhibited the infection compared to normal controls (see Table 1 and 2). It is known that IGF-2 binds to mannose-6-phosphate receptor (IGF-2/Man6-p receptor, see Specification pages 4-5). The prior art anticipated the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

10. No claims are allowed.

Conclusion

11. This application contains claims 9-16 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

2/2/03

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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